



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; comment request (30-Day FRN):

Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI)

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collected below. This proposed information collection was previously published in the Federal Register on September 20, 2012 (77 FR 58401) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after March 1, 2011, unless it displays a valid OMB control number.

Written comments or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response times, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at OIRA_submission@omb.eop.gov or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and

instruments, contact Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301-496-5725 or E-mail your request, including your address to: Hallch@mail.nih.gov.

Comments regarding this information collection are best assured of having their full effect if received within 30 days following the date of this publication.

Proposed Collection: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI), OMB No.0925-0613, Expiration Date: 2/28/2013, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI) responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials and to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug and the response of the patient to that drug. Investigators are physicians who specialize in the treatment of patients with cancer. Data obtained from the Drug Accountability Record is used to track the dispensing of investigational anticancer agents from receipt

from the NCI to dispensing or administration to patients. NCI and/or its auditors use this information for compliance purposes.

OMB approval is requested for 3 years. There are no costs to the respondents other than their time. The total estimated annualized burden hours are 14,328.

Estimates of Annual Burden					
Type of Respondents	Form Name	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in Hours)	Total Annual Burden Hour
Investigators and Designee for Investigator Registration and DARF	Statement of Investigator	20,220	1	15/60	5,050
	Supplemental Investigator	20,112	1	10/60	3,352
	Financial Disclosure	20,800	1	5/60	1,733
	Electronic Curriculum Vitae	100	1	15/60	25
	Drug Accountability Record Form (DARF and DARF-Oral)	3,907	16	4/60	4,168
Totals					14,328

Dated: February 11, 2013

Vivian Horovitch-Kelley

National Cancer Institute Project Clearance Liaison

National Cancer Institute, National Institutes of Health.

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